

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 859220-3	<b>FOR FURTHER ACTION</b> <small>see Form PCT/ISA/226 as well as, where applicable, item 5 below</small>	
International application No. PCT/JP99/11915	International filing date (day/month/year) 08 April 2000 (08.04.2000)	(Earliest) Priority date (day/month/year) 09 April 2004 (09.04.2004)
Applicant THIENNA, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the Report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).



- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I

2.



Certain claims were found unsearchable (See Box No. II)

3.



Unity of invention is lacking (See Box No. III)

4.



With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5.



With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6.



With regard to the drawings,

- a. The figure of the drawings to be published with the abstract is Figure No. ....



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.



none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/11915

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(Int) : A61K 7/135, 7/09; A61N 25/34 US CL : 424/62, 401, 464, 402 According to International Patent Classification (IPC) or to both national classification and IPC																
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 424/62, 401, 464, 402  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  Electronic data base consulted during the international search (name of data base used, where practicable, search terms used) Please See Communication Sheet																
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <table border="1"> <thead> <tr> <th>Category *</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X ---</td> <td>US 5,971,878 (HERSCHLER) 10 December 1991 (12.10.1991), column 7, line 65 - column 10; column 10, lines 12 - 57; column 11, line 40 - column 12, line 39.</td> <td>1-5 6-12, 17-20</td> </tr> <tr> <td>X ---</td> <td>US 4,296,130 (HERSCHLER) 20 October 1981 (10.20.1981), abstract, column 2, line 59 - column 4, line 16; Examples</td> <td>1, 2, 6, 7, 9, 10, 17-20 3-5, 8, 11-13</td> </tr> <tr> <td>X ---</td> <td>US 6,573,299 B1 (PETRUS) 03 June 2003, (06.03.2003), Table 1; column 5, line 53 - column 6, line 38; column 11, line 54 - column 12, line 7.</td> <td>1-7, 9-20 2</td> </tr> <tr> <td>Y</td> <td>ANSEL, H. Pharmaceutical Dosage Forms and Drug Delivery Systems, (1990 5th ed.), Lea &amp; Febiger, pages 310-320.</td> <td>8</td> </tr> </tbody> </table>		Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X ---	US 5,971,878 (HERSCHLER) 10 December 1991 (12.10.1991), column 7, line 65 - column 10; column 10, lines 12 - 57; column 11, line 40 - column 12, line 39.	1-5 6-12, 17-20	X ---	US 4,296,130 (HERSCHLER) 20 October 1981 (10.20.1981), abstract, column 2, line 59 - column 4, line 16; Examples	1, 2, 6, 7, 9, 10, 17-20 3-5, 8, 11-13	X ---	US 6,573,299 B1 (PETRUS) 03 June 2003, (06.03.2003), Table 1; column 5, line 53 - column 6, line 38; column 11, line 54 - column 12, line 7.	1-7, 9-20 2	Y	ANSEL, H. Pharmaceutical Dosage Forms and Drug Delivery Systems, (1990 5th ed.), Lea & Febiger, pages 310-320.	8
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<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																
* Special categories of cited documents "A" document defining the general state of the art which is not considered to be of particular relevance "B" earlier application or patent published on or after the international filing date "C" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "D" document referring to an oral disclosure, use, exhibition or other means "E" document published prior to the international filing date but later than the priority date claimed	"F" later documents published after the international filing date or priority date and not in conflict with the appearance but cited in order to show principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "R" document member of the same patent family															
Date of the actual completion of the international search 26 May 2005 (26.05.2005)	Date of mailing of the international search report 14 JUN 2005															
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Communication for Patents P.O. Box 1496 Alexandria, Virginia 22313-1496 Facsimile No. (703) 305-3236	Authorized officer Steven Padmalathan Telephone No. 703-308-1234															

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US05/11915

Continuation of B. FIELDS SEARCHED Item 3:  
WEST  
methylsulfonylmethane, methyl sulfonyl methane, akin

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
JONATHAN A. JAECH  
OMELVENY & MYERS LLP  
400 SCRIPPS HOPE STREET  
LOS ANGELES, CA 90071-2899

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) **14 JUN 2005**

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference

\$59829-3

International application No

PCT/US05/11915

International filing date (day/month/year)

08 April 2005 (08.04.2005)

Priority date (day/month/year)

09 April 2004 (09.04.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 7/135, 7/00; A61K 23/34 and US Cl.: 424/62, 401, 404, 402

Applicant

THIENNA, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

JUN 20 2005

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 12 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22311-1450

Transmittal No. (703)345-3230

Authorized officer

Screened Patentability

Telephone No. 703-308-1234

Form PCT/ISA/237 (cover sheet) (January 2004)

OMELVENY & MYERS LLP

File

Attorney

Date

Printed Name

2/18/05

2/18/05

2/18/05

2/18/05

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US95/11915

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(f)).

2. With regard to any nucleotide and/or amino acid sequences disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US95/11915

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statements

Novelty (N)	Claims 8	YES
	Claims 1-7, 9-20	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-20	NO
Industrial applicability (IA)	Claims 1-20	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Herschler (US 5071878).

Herschler discloses oral administration of methylsulfonylmethane (MSM) up to the amount of 300mg/kg body weight of animals. The reference also teaches adding vitamins to the composition. Examples 13 and 23 illustrate taking the diet supplement in the amount of 100-1000 mg per day to treat skin condition. The claimed method of lightening skin is inherently practiced by the prior art method.

Claims 1, 2, 6, 7, 9, 10, 17-20 lack novelty under PCT Article 33(2) as being anticipated by Herschler (US 4296130).

Herschler discloses topical and oral administration of MSM to beautify the complexion, improve the condition of the skin, increase skin softness and smoothness. The claimed method of lightening skin is inherently practiced by the prior art method.

Claims 1-7, 9-20 lack novelty under PCT Article 33(2) as being anticipated by Petrus (US 6,573,999).

Petrus discloses topical and oral administration of MSM as an anti-inflammatory and moisturizer which also enhances softness and rejuvenation of dry, aging or damaged skin. The claimed method of lightening skin is inherently practiced by the prior art method.

Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over prior art as applied in the immediately preceding paragraph and further in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery System).

Petrus fails to teach delivering the composition via patch form. Ansel teaches that transdermal delivery controls the rate of the drug delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Petrus invention by making a patch comprising the MSM composition as motivated by Ansel because the latter teaches that a transdermal device serves the rate-controlling mechanism in the drug delivery.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in cosmetic industry.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

international application No.

PCT/US05/11915

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 13-16 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s): It is not clear what applicants mean to include in the term "exfoliate". The claims are vague and indefinite also because the claims fail to recite the method step of how the "delivering an exfoliate" is carried out.

Claims 17-20 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s): The term "at least about daily" renders the claims vague and indefinite because the metes and bounds of the scope of the claim is not clear.